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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
08/860,007	08/04/1997	RALF BERSCHEID	62-209-45694	8493	
20736 7	7590 04/24 / 2003				
MANELLI DENISON & SELTER			EXAMINER		
2000 M STREET NW SUITE 700 WASHINGTON, DC 20036-3307			SHIPPEN, M	SHIPPEN, MICHAEL L	
			ART UNIT	PAPER NUMBER	
			1621	26	
			DATE MAILED: 04/24/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
		BERSCHEID, ET AL.				
Office Action Summary	08/860,007	Art Unit				
Office Action Cummary	Examiner	1621				
The MAILING DATE of this communication app	MICHAEL L. SHIPPEN ears on the cover sheet with					
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive to communication(s) filed on January 29,2003 by the Board of Appeals.						
2a) ☐ This action is FINAL . 2b) ☑ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	Ex parte Quayle, 1935 C.D.	11, 433 O.G. 213.				
4)⊠ Claim(s) <u>8,13,14,16-18,21-26 and 33-35</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>8,13,14,16-18,21-26 and 33-35</u> is/are rejected.						
7) ☐ Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domesti						
Attachment(s)						
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	5) Notice of Info	mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152) .				

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DETAILED ACTION

In view of the remand by the Board of Patent Appeals and Interferences of January 29, 2003, PROSECUTION IS HEREBY REOPENED. Consideration of the issues stated in the remand is set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
 - (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 1121

Claim 26 is rejected under 35 U.S.C. § 112, first and second paragraphs, for reasons set forth in the Examiner's Answer of Paper No. 19². It is noted in their remand the board suggested

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Appellant regards as his invention.

¹ The following is a quotation of the first paragraph of 35 U.S.C. 112:

² The process steps as recited in the claim will not afford products wherein n is 2. A process for carrying out the claimed process to afford such products is not disclosed nor enabled in the specification as filed.

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that Examiner and Appellant work together to clarify the scope of the claim. While believed to be self-evident, it is suggested to Appellants that the rejection can be overcome by limiting the claim to "n=1". Regarding the board's reference to the process as set forth on page 9 of the specification, this process is not before the Examiner and has not been examined. It being noted that Appellants have chosen not to present claims directed to the process of page 9 of the specification and chose instead to ague that adequacy of the instant claim as presented. As such

The issue here is directed to the preparation of the products of the formula I given in claim 26 wherein n = 2. The recited process starts with a malonic acid diester (step a) which through a series of steps affords a 3-aryl-substituted propanoic acid which is reduced to the desired alcohol of formula I (step d). This process is shown schematically on page 7 of Appellants' specification. It should be noted that the product is a 3-aryl-substituted propan-1-ol (e.g., n = 1). Since the process requires the use of a malonic acid diester starting material and reduction of a 3-aryl-substituted propanoic acid, the specific steps recited will not afford a 4-aryl-substituted butan-1-ol (e.g., n = 2). However, the claim reads on preparing products wherein n = 2 by the steps specifically recited (i.e., reducing the 3-aryl-substituted propanoic acid to form the desired alcohol of formula I). As such, the claim must be considered to read on processes that are not disclosed or enable.

While page 9 teaches a method of preparing compounds wherein n is 2, the process of page 9 is not being claimed here. The question here is not simply how does one prepare compounds of formula I when n = 2, but rather how does one prepare compounds of formula I when n = 2 according to the claimed process. The disclosure on page 9 does not answer this question. Note the process of page 9 does not use the reaction steps required by the claim and is inconsistent with claim step (d) which requires that compound of formulae I be prepared from a 3-aryl-substituted propanoic acid. While the process of page 9 does show a reduction step, the reduction involves a 4-aryl-substituted butanoic acid and not the required 3-aryl-substituted propanoic acid. As the claim presently reads, it reads on a process wherein products where n is 2 are obtained by the process steps specifically recited in the claims which is not enabled. It is particularly noted that Appellants admit that a different starting material is required to obtain the product when n = 2 as compared to the process when n = 1, see next to the last full paragraph of page 12 of Appellants' brief Paper No. 18.

Even if one was to find that the <u>claimed</u> process is enabled and described by the disclosure of page 9, one would have to conclude the claim fails to particularly point out the invention. None of the steps, reactants or reagents shown on page 9 are recited in the claim. It is readily apparent that such steps, reactants and reagents are critical to a process for the preparation of products when n = 2.

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further comment on the merits of the process as disclosed on page 9 of the specification is not appropriate since such a process is not before the Examiner³.

Claim Rejections - 35 USC § 1034

Claims 8, 14, 16-18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOPP (USP 4,110,430) for reason set forth in the Examiner's Answer of Paper No. 19⁵.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

³ The Examiner is not suggesting that if Appellants submit claims to such a process, such claims will be examined. The examination of newly presented claims drawn to an invention not presently under examination at this late stage in the prosecution would be unnecessarily burdensome upon the Examiner. It would clearly require additional searching and consideration of possible new grounds of rejections. Accordingly, any newly presented claims drawn to an invention not presently being examined may be subject to restriction in accordance with 37 CFR 1.499 under PCT Rule 13.1 and may be held withdrawn from consideration.

⁴ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

⁵ The reference teaches active agents that differ from the active agent recited in the claims only as to the position of the alkyl group on the benzene ring, note the compounds of formula I. Such agents are isomeric and so structurally similar that one would expect the respective agents to possess a community of properties in common rendering such a modification of the prior art compounds obvious. Further, the prior art active agents are homologous to the claimed compounds with respect to the alkyl group on the benzene ring, the R₁ group, the R₂ group and/or the value of n. Homologues are a class of compounds differing only by methylene linkages and

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In the remand the board indicate they have difficulty understanding the Examiner's reasoning and have instructed the Examiner to adhere to the model set forth in MPEP 706.02(j)⁶

possessing similar structures. Compounds of a homologous series are recognized as possessing a community of properties in common. Accordingly, it would have been obvious to one or ordinary skill in the art to interchange of these homologous substituents in the prior art active agent would afford closely related structures and agents possessing similar properties.

It is of no moment that the prior art does not teach all the same activity or utility for the prior art compounds as that described by Appellants. The skilled artisan need possess only some motivation to modify the prior art compound, and that such motivation need not coincide with the one driving an Appellant. The motivation is related to the uses one skilled in the art would expect that compound to have upon analyzing the prior art. That an Appellant comes upon a use of a compound that is not taught by the prior art does not speak to the compound's nonobviousness. *In re Shetty*, 195 USPQ 753 (CCPA 1977); *In re Lintner*, 173 USPQ 560 (CCPA 1972); *In re Hoch*, 166 USPQ 406 (CCPA 1970).

The tables set forth in the specification have been carefully considered but not found persuasive of patentability. The tables do not make any direct comparison of a prior art compound with the structurally closest claimed compounds. As such there is no evidence that the claimed compounds possess unexpectedly superior properties or properties different from the prior art.

⁶ 706.02(j) Contents of a 35 U.S.C. 103 Rejection

35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
 - (B) the difference or differences in the claim over the applied reference(s),
 - (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the

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to explain the rejection to the board. This section of the MPEP states in part the Examiner should set forth:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

ITEM (A) As has been indicated in the Examiner's Answer, HOPP teaches the claimed compositions and use thereof using active agents of formula I. As is readily seen from the picture of formula I in column 1 of the reference, the active agents of HOPP of formula I have the structure

references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections.

Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection. See In re Hoch, 428 F.2d 1341, 1342 n.3 166 USPQ 406, 407 n. 3 (CCPA 1970).

It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply. Furthermore, if an initially rejected application issues as a patent, the rationale behind an earlier rejection may be important in interpreting the scope of the patent claims. Since issued patents are presumed valid (35 U.S.C. 282) and constitute a property right (35 U.S.C. 261), the written record must be clear as to the basis for the grant. Since patent examiners cannot normally be compelled to testify in legal proceedings regarding their mental processes (see MPEP § 1701.01), it is important that the written record clearly explain the rationale for decisions made during prosecution of the application.

See MPEP § 2141 - § 2144.09 generally for guidance on patentability determinations under 35 U.S.C. 103, including a discussion of the requirements of Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966). See MPEP § 2145 for consideration of applicant's rebuttal arguments. See MPEP § 706.02(1) - § 706.02(1)(3) for a discussion of prior art disqualified under 35 U.S.C. 103(c).

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wherein R represents isopropyl or tert.butyl. The structures of these prior art species can be pictured as

and

One looking at HOPP will readily note that these active agents are disclosed throughout the six column reference as being useful in germ-inhibiting agents and deodorant compositions⁷. It is also without difficulty noted by one looking at the reference that throughout the reference mention is made of variety carriers⁸ including alcohols (ethanol, isopropanol, propylene glycol at lines 17-18 of column 2; alcoholic solution at line 61 of column 2, ethanol in Examples 1 and 2), solvents (first two full paragraphs of column 2 and the Examples) and surfactants (soaps at line 26 of column 2 and Examples 3 and 4; and agents such as glyceride mixture, fatty acid

⁷ Note the title, the abstract, the first, fourth, seventh and eight full paragraph and last paragraph of column 1, Examples 1-6, and the claims of the reference.

⁸ Note entire column 2, Examples 1-6 and claim 5 of the reference.

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amidomethyl betaine and the sodium laurylether sulphate of Examples 5 and 6 all of which are surfactants).

ITEM (B) As also indicated in the Examiner's Answer, the prior art active agent differs from what is claimed only as to the position of the alkyl group on the benzene ring or in a homologous manner. This is apparent from by looking at instant claims 14, 21, 22 and 24.

Claim 14 reads, *inter alia*, on a composition comprising an alcohol, solvent <u>or</u> surfactant and a compound of the formula

wherein

 R_1 may be hydrogen, or C_{1-8} alkyl R_2 may be C_{1-8} alkyl R_3 - R_7 may be hydrogen or C_{1-8} alkyl, and n is 1 or 2 provided

- (i) when R₁ and R₃-R₇ are hydrogen, then n is 2;
- (ii) when R₁ and R₂ are C₁₋₆ alkyl and
 - a)R₃-R₇ are hydrogen, or
 - b) R₅ is methyl and R₃, R₄, R₆, R₇ are hydrogen, then n is 2;
- (iii) when R_1 , R_2 and R_4 are methyl and R_3 and R_5 - R_7 are hydrogen, then n is 2;
- (iv) when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2;
- (v) when R_1 , R_3 , R_6 and R_7 are hydrogen, R_2 is methyl and R_4 and/or R_5 are hydrogen or C_{1-6} alkyl, then n is 2;
- (vi) when R_1 and R_4 - R_7 are hydrogen, R_2 is methyl or ethyl and R_3 is methyl, then n is 2; and
- (vii) when R_1 , R_3 , R_5 and R_7 are hydrogen, R_2 is methyl, R_4 and R_6 are methyl or R_4 is hydrogen, and R_6 is methyl, then n is 2;

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Claim 21 reads, inter alia, on a shampoo or shower gel comprising

an alcohol, solvent or surfactant,

a re-fatting agent

and a compound of the formula

$$R_5$$
 R_4
 R_3
 R_4
 R_3
 R_4
 R_3
 R_4
 R_5

wherein

 R_1 may be hydrogen, or C_{1-8} alkyl R_2 may be C_{1-8} alkyl R_3 - R_7 may be hydrogen or C_{1-8} alkyl, and n is 1 or 2

provided

when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2;

Claim 22 and 24 read, *inter alia*, method comprising apply to a surface a composition comprising an alcohol, solvent <u>or</u> surfactant

and a compound of the formula

$$R_5$$
 R_7
 R_1
 R_5
 CH_2
 CH_2
 CH_2
 R_3
 R_2

wherein

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 R_1 may be hydrogen, or C_{1-8} alkyl R_2 may be C_{1-8} alkyl R_3 - R_7 may be hydrogen or C_{1-8} alkyl, and n is 1 or 2

provided

when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2.

One would recognize that the claims read on compositions and their use containing the active agent wherein R_1 , R_3 , R_4 , R_5 and R_7 are hydrogen, R_2 is methyl⁹ and R_6 is isopropyl or tert-butyl¹⁰, and n is 1. These claimed active agents have the structures which can be pictured as

CLAIMED ACTIVE AGENT 1

CLAIMED ACTIVE AGENT 2

The structural relationship of these claimed active agents compared to the HOPP active agents is characterized as "positional isomers". Those familiar with the chemical practice understand that this means the isopropyl or tert-butyl group is bonded to different carbons of the phenyl ring¹¹ in the respective compounds as which can be readily seen by comparing the respective pictures thereof.

⁹ Methyl is a C₁ alkyl group and within the purview of the claimed C₁₋₈ alkyl group.

 $^{^{10}}$ Isopropyl is a C_3 alkyl group and tert-butyl is a C_4 alkyl and within the purview of the claimed $\text{C}_{1\text{--}8}$ alkyl group.

¹¹ The phenyl ring is shown as or in the structural formulae above

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HOPP ACTIVE AGENT 1

HOPP ACTIVE AGENT 2

In addition, one can also identify a number of claimed active agents that are homologues¹² of the prior art active agents. There are a number of adjacent homologues^{13,14} such as:

¹² Homologues are compounds that differ by methylene (-CH₂-) linkages.

¹³ A homologue that differs by only a single methylene linkage.

¹⁴ The methylene linkage is indicated by the CH₂ group.

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ITEM (C) As indicated in the Examiner's Answer, the proposed modification of the reference is to interchange these structurally similar positional isomers or homologues in the prior compositions and methods of use.

ITEM (D) One of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed modification. As has already been indicated in the Examiner's Answer, one would expect the respective agents to possess a community of properties in common in view of the close structurally similarity pointed out above. That is one would expect to obtain additional active agents having the prior art use by such a modification of the prior art active agents. See *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). For further illumination one is referred to MPEP 2144.09.

In the remand the board also pointed to the fact that the Examiner did not address each claim separately in spite of the fact that the claims stood or fell together, 37 CFR 1.192(c)(7)¹⁵.

¹⁵ 37 CFR § 1.192 (c)(7)

Grouping of claims. For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable. (emphasis added)

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Claim 8 depends from claim 14 and specifies that the composition contains 0.01 to 10% of the active agent and 0.1 to 90% of an additional agent. The claimed range is clearly within the amounts specified by the reference (note third full paragraph of column 2) and embraces the amounts exemplified in the Examples 1-6 of the reference. It would readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 14 has been addressed fully and separately above.

Claim 16 depends from claim 14 and specifies that the composition contains 0.01 to 10% of the active agent. The claimed range is clearly within the amounts specified by the reference (note third full paragraph of column 2) and embraces the amounts exemplified in the Examples 1-6 of the reference. It would readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 17 depends from claim 14 and specifies that the composition contains 0.05 to 8% of the active agent. The claimed range is clearly within the amounts specified by the reference (note third full paragraph of column 2) and embraces the amounts exemplified in the Examples 1-6 of the reference. It would readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 18 depends from claim 14 and specifies that the composition contains 0.1 to 5% of the active agent. The claimed range is clearly within the amounts specified by the reference (note third full paragraph of column 2) and embraces the amounts exemplified in the Examples 1-6 of

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the reference. It would readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

While claim 21 has been address separately above, the board point specifically to the claim reference to a "re-fatting agent" ¹⁶. The claimed component is clearly within the components in compositions specified by the reference note second full paragraph of column 2 and the compositions exemplified in the Examples 1-6 of the reference. It would readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference including use in the compositions containing re-fatting agents.

Claim 22 has been addressed fully and separately above.

Claim 24 has been addressed fully and separately above.

Claim 25 depends from claim 24 and specifies that the surface treated is skin. HOPP refers to cosmetic 17 compositions throughout the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same cosmetic compositions and in the same manner specifically taught by the reference.

It is noted that in their reply brief of Paper No. 22 Appellants submitted additional evidence in the form of screening tests and a reference written in a foreign language. The screening test data is not presented in proper form, see 37 CFR 1.132. As such it has been given

¹⁶ A re-fatting agent is an agent added to cosmetics, particularly cleansing agents, to relieve their drying effects and includes agents such as isopropyl myristate, propylene glycol and Softigen®.

¹⁷ It is believed that everyone recognizes that a cosmetic would be a composition applied to body surfaces, particularly the skin.

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little weight in consideration of the patentability of the instant claims. The reference is not in English and a translation was not provided. As such, the reference has not been considered. It is further noted, that the assertion of one expecting similar properties in view of the close structural similarity of the instant active agents to those of the prior art is not an assertion of identical properties but rather similar properties. After all the agents are not identical in every respect and one would not expect identical properties.

Claims 8, 13, 14, 16-18, 21-25 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over SIPOS (USP 4,321,257) for reasons set forth in the Examiner's Answer of Paper No. 19¹⁸.

¹⁸ The reference generically teaches the claimed compounds or active agents, note the phenyl alkanols given at the bottom of column 4. Also, note the agents specifically referred to in lines 43-51 of column 5. The reference does not specifically exemplify the instant compound. However, the generic teaching indicates to one of ordinary skill in the art that species falling within the generic disclosure, including the instantly claimed compound, would possess the prior art use. It is well within the skill of the artisan to select among the alternatives of the reference to afford compounds possessing the prior art use, *In re Lemin*, 141 USPQ 814.

Also, the reference teaches active agents that differ from the active agent recited in the claims only as to the position of the substituents on the benzene ring. Such agents are isomeric and so structurally similar that one would expect the respective agents to possess a community of properties in common render such a modification of the prior art compounds obvious. Furthermore, the prior art active agents are homologous to the claimed compounds with respect to the alkyl groups on the benzene ring, the R₁ group, the R₂ group and/or the value of n. Homologues are a class of compounds differing only by methylene linkages and possessing similar structures. Compounds of a homologous series are recognized as possessing a community of properties in common. Accordingly, it would have been obvious to one or ordinary skill in the art to interchange of these homologous substituents in the prior art active agent would afford closely related structures and agents possessing similar properties.

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Adhering to the guidelines set forth in the record MPEP 706.02(j):

ITEM (A) As has been indicated in the Examiner's Answer, the reference generically teaches the claimed compounds or active agents, note the phenyl alkanols given at the bottom of column 4. Also, note the agents specifically referred to in lines 43-51 of column 5. As is readily seen in the picture in bottom of column 4 of the reference, SIPOS generically teaches agents having the structure that can be pictured as

$$R_4 \longrightarrow \begin{bmatrix} R_5 & R_5 & R_6 \\ I & I & C \\ C & C & C \\ I & I & I \\ R_5 & R_5 & R_7 \end{bmatrix}_m OH$$

wherein, inter alia, m may be 1; R_4 may be halogen¹⁹ or C_1 to C_4 alkyl; and R_5 , R_6 and R_7 may be independently hydrogen or C_1 to C_3 alkyl wherein the total of carbon atoms in the structure

$$\begin{array}{c|cccc}
R_5 & R_5 & R_6 \\
I & I & C \\
C & C & C \\
I & I & R_7
\end{array}$$

$$\begin{array}{c|cccc}
R_6 & I & C \\
C & C & C \\
R_7 & R_7
\end{array}$$

is 3 to 9 carbon atoms. Also, in lines 43-51 of column 5, agents specifically referred to that may be pictured as

It is of no moment that the prior art does not teach all the same activity or utility for the prior art compounds as that described by Appellants. The skilled artisan need possess only some motivation to modify the prior art compound, and that such motivation need not coincide with the one driving an Appellant. The motivation is related to the uses one skilled in the art would expect that compound to have upon analyzing the prior art. That an Appellant comes upon a use of a compound that is not taught by the prior art does not speak to the compound's nonobviousness. In re Shetty, supra; In re Lintner, supra; In re Hoch, supra.

The tables set forth in the specification have been carefully considered but not found persuasive of patentability. The tables do not make any direct comparison of a prior art compound with the structurally closest claimed compounds. As such there is no evidence that the claimed compounds possess unexpectedly superior properties or properties different from the prior art.

¹⁹ Halogen is known in to those familiar in the art to be the elements in the Group VIIA of the Periodic Table, e.g., fluoro (-F), chloro (-Cl), bromo (-Br).

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These active agents are disclosed in the reference as being useful in antimicrobial compositions²⁰. It is readily noted by one looking at the reference that throughout the reference mention is made of variety carriers²¹ including alcohols (ethanol in the Examples). Throughout the reference the compositions are indicated as being used topically²².

ITEM (B) As also indicated in the Examiner's Answer, the prior art differs from what is claims only in that the reference is generic and/or teaches compounds, compositions and their use wherein the an active agent is a structurally similar positional isomer or homologue. This is readily apparent from by looking at instant claims 13, 14, 21, 22 and 24.

²⁰ Note at the bottom of column 5 through column 9.

²¹ Note the second full paragraph of column 6 and the third full paragraph of column 9.

²² Topical application is known to mean application to the surface of the body such as the skin.

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Claim 13 reads on compounds that have the structure that may be pictured as

wherein n can be 1 or 2.

Claim 14 reads, *inter alia*, on a composition comprising an alcohol, solvent <u>or</u> surfactant and a compound of the formula

$$R_{5}$$
 R_{7}
 R_{1}
 R_{1}
 R_{5}
 R_{2}
 R_{4}
 R_{3}
 R_{2}
 R_{2}
 R_{1}
 R_{1}
 R_{2}
 R_{3}
 R_{2}

wherein

 R_1 may be hydrogen, or C_{1-8} alkyl

R₂ may be C₁₋₈ alkyl

R₃-R₇ may be hydrogen, halogen or C₁₋₈ alkyl, and

n is 1 or 2

provided

- (i) when R_1 and R_3 - R_7 are hydrogen, then n is 2;
- (ii) when R₁ and R₂ are C₁₋₆ alkyl and

a)R₃-R₇ are hydrogen, or

- b) R₅ is methyl or chloro and R₃, R₄, R₆, R₇ are hydrogen, then n is 2;
- (iii) when R₁, R₂ and R₄ are methyl and R₃ and R₅-R₇ are hydrogen, then n is 2;
- (iv) when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2;
- (v) when R_1 , R_3 , R_6 and R_7 are hydrogen, R_2 is methyl and R_4 and/or R_5 are hydrogen or C_{1-6} alkyl, then n is 2;
- (vi) when R₁ and R₄-R₇ are hydrogen, R₂ is methyl or ethyl and R₃ is methyl, then n is 2; and

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(vii) when R_1 , R_3 , R_5 and R_7 are hydrogen, R_2 is methyl, R_4 and R_6 are methyl or R_4 is hydrogen, and R_6 is methyl, then n is 2;

Claim 21 reads, inter alia, on a shampoo or shower gel comprising

an alcohol, solvent or surfactant,

a re-fatting agent

and a compound of the formula

$$R_5$$
 R_7
 R_1
 R_1
 R_2
 CH_2
 CH_2
 CH_2
 R_3
 R_2
 R_3
 R_2

wherein

 R_1 may be hydrogen, or C_{1-8} alkyl R_2 may be C_{1-8} alkyl R_3 - R_7 may be hydrogen, halogen or C_{1-8} alkyl, and n is 1 or 2

provided

when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2;

Claim 22 and 24 read, *inter alia*, method comprising apply to a surface a composition comprising an alcohol, solvent <u>or</u> surfactant

and a compound of the formula

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$$R_6$$
 R_7
 R_1
 CH_2
 CH_2
 CH_2
 R_3
 R_2

wherein

 R_1 may be hydrogen, or C_{1-8} alkyl R_2 may be C_{1-8} alkyl R_3 - R_7 may be hydrogen, halogen or C_{1-8} alkyl, and n is 1 or 2

provided

when R_1 , R_3 , R_4 , R_6 and R_7 are hydrogen and R_5 is methyl, isopropyl or tert-butyl, then n is 2.

One would recognize that the claims read on compounds, compositions and their use containing as active agent that with the generic disclosure of the reference. For example, the claims read on compounds and active agents that overlap the genus of the reference within a group of agents that may be represented by the formula pictured as

wherein R_4 may be halogen or C_1 to C_4 alkyl; and the R_5 's may be independently hydrogen or C_1 to C_3 alkyl. In particular, besides the positional isomers and adjacent homologues discussed below, the claims read on agents within the prior art genus that are very similar to the specific agents disclosed such as halogen analogs and other homologues. For example,

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As also indicated in the Examiner's Answer, the claims read on positional isomers of the agents disclosed in the reference. For example,

The structural relationship of these claimed active agents compared to the SIPOS active agents is characterized as "positional isomers". Those familiar with chemical practice understand that this

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means the chloro group on the phenyl ring in different positions in the respective compounds as which can be readily seen by comparing the pictures of the prior art compound set forth above.

Further, as has been indicated in the Examiner's Answer, the claims also read on agents that differ only in a homologous manner. There are a number of adjacent homologues such as:

ITEM (C) The proposed modification of the reference is for 1) one to use the specific active agents disclosed (i.e., the specific agents listed in lines 43-51 of column 5) in the reference in compositions of the prior art in the manner the reference specifically teaches, 2) for one to use agents that are within the genus of the reference in the compositions and methods in the manner specifically taught by the reference and/or 3) to interchange structurally similar positional

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isomers or homologues of the prior art active agents and to use such in the compositions and methods of the prior art in the manner the reference specifically teaches one to do.

ITEM (D) One of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed. First, the reference specifically suggest to one to do such²³ and one would clearly expect to obtain the results specifically taught by the reference. Second, one would expect other species within the genus to be used in the same manner since this is what the reference itself suggest. Third, the homologues and positional isomers of the prior art active agents would be expected to possess a community of properties in common because of the close structurally similarity pointed out above. That is one would expect to obtain additional active agents having the prior art use by such a modification of the prior art. See In re Payne, supra; In re Papesch, supra and In re Dillon, supra. For further illumination one is referred to MPEP 2144.09. The teaching of equivalence of the homologues is reinforced by the teaching of the reference itself. SIPOS indicates that the R₄ group may be an alkyl of C₁ to C₄ and the R₅ group may be an alkyl of C₁ to C₃, which embraces methyl, ethyl, propyl, and butyl, which is a homologous series. The reference clearly indicates that the homologues are considered to be equivalents, i.e., possess similar properties. The teaching of equivalence of the positional isomers is reinforced by the reference teaching that the R₄ group is attached by a floating bond²⁴ in the formula. The reference clearly suggests that active agents having the R₄

²³ Note the specific agents listed in lines 43-53 of column 5 specifically picture above are within the purview of the active agents of claims 21, 22 and 24.

 $^{^{24}}$ The bond is not attach to a specific carbon atom on the phenyl ring. This is recognized in the art to be a floating bond and is recognized to indicated that the R_4 may be attached to any available carbon atom on the phenyl ring.

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group at different positions on the phenyl ring are considered equivalent, i.e., possessing similar properties.

Claim 8 depends from claim 14 and specifies that the composition contains 0.01 to 10% of the active agent and 0.1 to 90% of an additional agent. The claimed range is clearly within the amounts specified by the reference (note the last paragraph of column 5) and embraces the amounts of potentiator agent²⁵ used in the examples of the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 13 has been addressed above. It is pointed out again, the claim reads on a compound within the genus of the compounds of the reference. Also, the claimed compounds are very structurally similar to specific compounds listed in that the claimed compound is an adjacent homologue and positional isomer of the SIPOS compound

For the same reasons discussed above, one would expect the claimed compound to possess similar properties to the prior art compound because of the close structural similarities of positional isomers and homologues as discussed above.

Claim 14 has been addressed fully and separately above.

Claim 16 depends from claim 14 and specifies that composition contains 0.01 to 10% of the active agent. The claimed range is clearly within the amounts specified by the reference (note the last paragraph of column 5) and embraces the amounts of potentiator agent used in the

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examples of the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 17 depends from claim 14 and specifies that composition contains 0.05 to 8% of the active agent. The claimed range is clearly within the amounts specified by the reference (note the last paragraph of column 5) and embraces the amounts of potentiator agent used in the examples of the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

Claim 18 depends from claim 14 and specifies that composition contains 0.1 to 5% of the active agent. The claimed range is clearly within the amounts specified by the reference (note the last paragraph of column 5) and embraces the amounts of potentiator agent used in the examples of the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same amounts and the same manner as specifically taught by the reference.

While claim 21 has been address separately above, the board point specifically to the claim reference to a "re-fatting agent". The claimed component is clearly within the components in compositions suggested by the reference note third full paragraph of column 9 and the compositions exemplified in the examples of the reference that make reference to agents such as propylene glycol and isopropyl myristate. It would be readily apparent to one of ordinary skill in

²⁵ The active agents in question here are characterized as potentiator agents in SIPOS.

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the art the claimed obvious active agents would be used in the same manner specifically taught by the reference.

Claim 22 has been addressed fully and separately above.

Claim 24 has been addressed fully and separately above.

Claim 25 depends from claim 24 and specifies that the surface treated is skin. The reference refers to topical compositions throughout the reference. It would be readily apparent to one of ordinary skill in the art the claimed obvious active agents would be used in the same topical compositions specifically taught by the reference.

Claim 33 depends from claim 14 and limits the active agent to

As pointed out above, this agent is within the genus suggested by the reference and is positional isomer and adjacent homologues of the specific species recited by the reference. For the same reasons discussed above, one would expect the instant active agent to possess similar properties and be used in the same manner as the agents taught in the reference.

Claim 34 depends from claim 14 and limits the active agent to

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As pointed out above, this agent is within the genus suggested by the reference and is positional isomer and adjacent homologues of the specific species recited by the reference. For the same reasons discussed above, one would expect the instant active agent to possess similar properties and be used in the same manner as the agents taught in the reference.

Claim 35 depends from claim 14 and limits the active agent to

As pointed out above, this agent is within the genus suggested by the reference and is adjacent homologues of the specific species recited by the reference. For the same reasons discussed above, one would expect the instant active agent to possess similar properties and be used in the same manner as the agents taught in the reference.

It is noted that in their reply brief of Paper No. 22 Appellants submitted additional evidence in the form of screening tests and a reference written in a foreign language. The screening test data is not presented in proper form, see 37 CFR 1.132. As such it has been given little weight in consideration of the patentability of the instant claims. The reference is not in

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English and a translation was not provided. As such, the reference has not been considered. It is further noted, that the assertion of one expecting similar properties in view of the close structural similarity of the instant active agents to those of the prior art is not an assertion of identical properties but rather similar properties. After all the agents are not identical in every respect and one would not expect identical properties.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over HAFNER (USP 4,968,668) in view of VOGEL (A Textbook of Practical Organic Chemistry) for reasons set forth in the Examiner's Answer of Paper No. 19²⁶.

²⁶ HAFNER teaches an analogous process that differs from the claimed process in that the prior art does not recite step (a) and some of the reactants differ as to the substituents present. HAFNER disclosed steps (b)-(d), note the schematic at the top of column 3, the discussion thereof and Example 3.

The recited step (a) is a standard textbook method of preparing the alkylmalonates that would be used in the HAFNER process. VOGEL clearly demonstrates that claim step (a) is a standard method of synthesis of a C-substituted malonic ester (see the bottom portion of page 483 and Example III,153). Also note VOGEL further suggest that the C-substituted malonic ester can be further reacted to form a C-disubstituted malonic ester (see the first full paragraph of page 484) which corresponds to claim step (b) and the first step of the HAFNER process. No patentable significance is seen in reciting a standard method of preparing a known starting material that would be used in the prior art process. Moreover, with respect to multi-step synthetic procedures involving a combination of individually well known chemical reactions, it has been held that one of ordinary skill in the relevant art is charged with knowledge of the individual chemical reactions and their combination to produce a desired end product would have been obvious, In re Payne, 203 USPQ 245; In re Winslow, 151 USPQ 48; In re Kamlet, 88 USPQ 106.

The differences in the reactants are found only in substituents that are removed from the reaction site and do not affect the outcome of the reaction. The reactive functional groups involved are the same and undergo the same conversion. The claimed process affords the products one would expect from the teaching of the prior art. The use of a new starting material in an otherwise old process is considered obvious

Assertions that the products possess unexpected properties are not found persuasive. The properties of the products are not the result of the method of preparation but rather the structural features of the products themselves regardless of the method of preparation.

The Examiner's conclusion of obviousness is not based upon improper hindsight reasoning. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 170 USPQ 209.

The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 5 USPQ2d 1596 and *In re Jones*, 21 USPQ2d 1941. As pointed out above, one would be motivated to prepare a necessary starting material by known, standard methods of synthesis.

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Adhering to the guidelines set forth in the record MPEP 706.02(j):

ITEM (A) As has been specifically pointed out in the Examiner's Answer, HAFNER teaches an analogous process that differs from the claimed process in that the prior art does not recite step (a) and some of the reactants differ as to the substituents present. That is, HAFNER disclosed steps (b)-(d), note the schematic at the top of column 3, the discussion thereof and Example 3. HAFNER teaches dialkylating a monoalkylated malonic acid ester (diethyl methylmalonate) with a benzyl halide (3-methylbenzyl chloride or 3,5-dimethylbenzyl chloride).

subsequently saponify and decarboxylating to form the corresponding 3-arylpropanoic acid

$$\begin{array}{c|c} \text{COOEt} \\ \text{X} & \text{CH}_2\text{CCH}_3 \\ \text{COOEt} & \rightarrow \\ \text{CH}_1 & \text{CH}_3 \\ \end{array}$$

and reducing to form the corresponding alcohol

$$X$$
 CH_2CHCH_3
 CH_2CHCH_3
 CH_2CHCH_3
 CH_2OH
 CH_3

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As indicated in the Examiner's Answer, VOGEL clearly demonstrates that claim step (a) is a standard method of synthesis of a C-substituted malonic ester (see the bottom portion of page 483 and Example III,153). Also note VOGEL further suggest that the C-substituted malonic ester can be further reacted to form a C-disubstituted malonic ester (see the first full paragraph of page 484) which corresponds to claim step (b) and the first step of the HAFNER process.

ITEM (B) As also indicated in the Examiner's Answer, HAFNER teaches an analogous process that differs from the claimed process in that the prior art does not recite step (a) and some of the reactants differ as to the substituents present.

ITEM (C) As indicated in the Examiner's Answer, the proposed modification of the reference is

1) prepare the starting material to be used in the HAFNER process by using the standard diethyl alkylmalonate synthesis as disclosed by VOGEL and 2) to use other analogous reactants to afford analogous products.

been motivated to make the proposed modification. First, inherent in any process is the necessity of obtaining the starting materials. This almost always necessitates the starting material to have been prepared by some synthetic method. Even a commercial product has been synthesized²⁷. One would be motivated to use a known method of synthesis since this would afford the starting material needed. This is merely common sense. Otherwise one would have to ignore the known methods of preparation and with the expenditure of a great deal of time and expense develop novel methods of preparations or reinvent the known methods of preparation. One would be

²⁷ Unless in the rare instance where the starting material occurs naturally. The starting materials involved here do not occur naturally.

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motivated to use analogous starting materials since one would expect to obtain additional useful products. While the specific products of HAFNER have been provisioned out of the claim, the claimed process still reads on products that are structurally obvious homologues and positional isomers of the prior art products, note the discussion of these concepts in the preceding rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael L. Shippen** whose telephone number is **(703) 308-4635**. The Examiner's normal tour of duty is 7:30 AM to 4:00 PM. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(703) 308-1235**. The official group FAX machine number is **(703) 308-4556**.

MShippen April 23, 2003

> MICHAEL L. SHIPPEN PRIMARY EXAMINER ART UNIT 1621